IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant	:	Stephen T. Dybing
App. No	:	10/646,852
Filed	:	August 22, 2003
For	:	METHOD FOR PRODUCING A FOOD PRODUCT FROM A CONCENTRATED PROTEIN
Examiner	:	Leslie A. Wong
Art Unit	:	1794
Conf No.	:	1515

REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is submitted in response to the Examiner's Answer with a notification date of June 24, 2010. The Examiner's Answer was in response to the Appeal Brief filed March 19, 2010, appealing from a Final Rejection set forth in an Office Action mailed August 20, 2009.

Status of the Claims begins on page 2 of this paper.

Grounds of Rejection to be Reviewed on Appeal begin on page 3 of this paper.

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STATUS OF THE CLAIMS

Claims 2-8, 10-13, 16-22, 27, and 33-45 are currently pending. Claims 1, 9, 14, 15, 23-26, and 28-32 were canceled. Claims 2-8, 10-13, 16-22, 27, and 33-45 were finally rejected by the Examiner, and are the subject of this appeal. A copy of the appealed claims is attached as the Claims Appendix.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 2-8, 10-13, 16-22, and 38-45 stand rejected under 35 U.S.C. § 102(e) as anticipated by WO 02/096208 to Carr (hereinafter "Carr").

B. Claims 2-8, 10-13, 16-22, and 38-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carr.

C. Claims 33-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carr in view of U.S. Patent No. 6,358,551 to Sadowsky (hereinafter "Sadowsky").

D. Claim 27 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Carr and Sadowsky.

E. Claims 39-45 stand rejected under 35 U.S.C. § 102(e) as anticipated by Carr.

F. Claims 39-45 stand rejected under 35 U.S.C. § 103 as unpatentable over Carr.

G. Claims 43-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carr and Sadowsky.

REMARKS

In the Final Office Action dated August 20, 2009, the Examiner rejected Claims 2-8, 10-13, 16-22, and 38-45 as anticipated or obvious in view of Carr. The Examiner rejected Claims 27 and 33-37 as unpatentable over Carr and Sadowsky.

The Examiner's Answer repeats the rejections from the Final Office Action of August 20, 2009 while also adding a few new statements and justifications for the rejections. Appellant addresses the new findings by the Examiner below.

Priority

The Examiner previously objected to the priority claim only on the basis of lack of support of monovalent salt in the provisional application. The entire priority analysis by the Examiner in the Final Office Action dated August 20, 2009 stated "It is noted that provisional application 60/405791 does not correspond to the current application. Specifically, 60/405791 is not directed to the addition of a monovalent salt. Applicant is not entitled to the priority date of the provisional application." Office Action dated August 20, 2009 at page 2. During prosecution, Appellant submitted that Claims 38, 2-8, 10-13, 16, and 27 do not recite monovalent salt. The Examiner did not address this argument during prosecution.

In the Examiner's Response to Appellant's appeal brief the Examiner has not addressed the Appellant's statements that Claims 38, 2-8, 10-13, 16, and 27 do not recite monovalent salt and has instead raised a ***new*** objection to the priority of the claims for failing to teach "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water." Examiner's Response, page 5. The Examiner further found that "Paragraph [0021] refers to ionic strength but there is no teaching of how the ionic composition would be adjusted or any reference to a monovalent salt. The provisional application does not teach any means to adjust the ionic strength." *Id.* The Examiner also found that the "provisional application 60/405791 does not describe adjustment of the ionic composition in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *Id.* Appellant notes that this is a new basis for rejection in the Examiner's Answer. Appellant submits that the adjustment of the ionic strength is clearly contemplated in the provisional application and that a person of skill in the art would know how to adjust the ionic

strength in view of the disclosure in the provisional application. Paragraph [0021] provides an example for adjusting the ionic strength and character of the ionic species. Paragraph [0021] of the provisional application 60/405791 is as follows (emphasis added):

> [0021] Upon preparation of the desired protein solution with the desired degree of hydration, ***the conformation of the proteins may be adjusted so as to optimize the ability of the proteins to emulsify fat***. Procedures that can be used to effectively modify the protein conformation include, but are not limited to adjustments in the solution temperature, pH, ***ionic strength and character of the ionic species, ion exchange***, water activity, and with specific enzymes. Particularly preferred alterations in protein conformation include the conversion of casein in the protein solution to sodium caseinate by the addition of acid to the isoelectric point (typically pH 4.6) followed by the ***absorption of sodium from a suitable carrier by ion exchange at a basic pH***.

Contrary to the Examiner's new findings, Paragraph [0021] clearly contemplates and enables a person of skill in the art to adjust the ionic composition of the hydrated protein solution. Further, sodium is a monovalent ion. Accordingly, Appellant submits that Claim 38 is clearly supported in the provisional application. *See also* paragraphs [0002], [0006], [0007], [0014], [0015], [0016], [0018], [0019], [0021], and [0022] and Figure 1 of Provisional patent application serial number 60/405,791. Also, Claims 38, 2-8, 10-13, 16, and 27 do not recite monovalent salt and are also clearly supported by the provisional patent application. Support for Claims 38, 2-8, 10-13, 16, and 27 can be found throughout the provisional application as filed, for example, in Figure 1, the claims, and paragraphs [0002], [0006], [0007], [0012], [0014], [0015], [0016], [0018], [0019], [0021], and [0022].

Appellant respectfully submits that at least Claims 38, 2-8, 10-13, 16, and 27 are entitled to the priority date of the provisional application.

Anticipation Rejections

Appellant again submits that Carr fails to anticipate the pending claims. Carr does not disclose the steps or order of steps recited in independent Claim 38. Carr fails to disclose explicitly or inherently "mixing the hydrated protein solution with a concentrated fat to form a first food product" as recited in Claim 38. On this basis alone, the rejection should be withdrawn. Carr also fails to disclose "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water". There is no disclosure in Carr regarding

emulsification properties. Enhancing the ability of the protein solution to emulsify fat is a meaningful physical change that is an explicit part of the claimed process and must be given patentable weight. Claim 38 clearly recites "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein".

Example 9 of Carr, relied on the by the Examiner, discloses adding fresh cream to fresh skim milk and subsequently adding various compositions of MPC85 to the mixture of fresh cream and fresh skim milk. Carr, page 9, ll. 13-25. Carr does not disclose adding salt to the mixture or otherwise disclose adjusting the ionic composition of the hydrated protein solution. None of the references explicitly or inherently disclose "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein" as claimed. Claim 38 itself clearly recites that the enhanced ability to emulsify fat in water as at least one of increased emulsion capacity and increased emulsion stability in comparison to untreated protein. This is not the same as enhanced solubility.

Since there is no explicit teaching regarding increased emulsion capacity in Carr, the Examiner is relying on inherency. However, the Examiner has only provided a conclusory statement which clearly does not meet the required burden for showing inherency. ("An increase in the emulsion capacity and stability would be no more than inherent and/or obvious to that of Carr as the same components and process steps are used", Office Action dated August 20, 2009 at page 3). When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic ***necessarily flows*** from the teachings of the applied prior art. *Ex parte* Levy, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

In an attempt to bolster the Examiner's previous conclusory statement that enhanced emulsification properties are inherent, the Examiner ***newly*** found that "Certainly as you enhance the solubility then you necessarily enhance 'the ability to emulsify.' If a protein were not soluble then it would be unable to emulsify. Any improvement in solubility would increase the ability to emulsify." Examiner's Response at page 6. The Examiner has provided no scientific basis for

this statement and, since it was raised for the first time in the Answer, Appellant has not had any opportunity to address it previously. Carr focuses on ***enhancing the solubility*** of dried MPC. Enhanced solubility and enhanced emulsification are ***not*** synonymous. The Examiner's statement uses the faulty logic that if a protein is not soluble then it would be unable to emulsify; therefore any improvement in solubility would necessarily increase the ability to emulsify. Carr is not concerned with increasing the solubility of MPC that is ***not*** soluble in water; instead Carr focuses on increasing the cold water solubility of dried MPC that ***already has some solubility*** in water. Thus, the Examiner's logic does not apply to the soluble MPC of Carr. The Examiner has provided no scientific basis to support the conclusory statements regarding inherency. The Examiner's new reasoning does not logically follow from Carr and is also not applicable to the teachings of Carr to show ***inherency*** for an ***anticipation*** rejection. Thus, even with the new rationale provide in the Examiner's Reply, the Examiner has failed to provide any scientific support for this conclusion and much less the necessary facts and technical reasoning required to legally support a finding of inherency.

Appellant has previously detailed technical reasons why increasing the solubility does not necessarily enhance the ability to emulsify in the Appeal Brief. The Examiner has not refuted or even addressed the technical reasons discussed by Appellant and has not provided a sufficient reasoning to meet the burden required to show that enhancing cold water solubility of the MPC of Carr necessarily increases the ability of the material to emulsify fat. Carr fails to inherently or explicitly disclose "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein".

As discussed above, Carr also fails to disclose other elements of the claims and does not teach the order of the steps.

Accordingly, because Carr does not teach, inherently or explicitly, each of the elements of the claims, Applicant respectfully request withdrawal of the anticipation rejection of Claims 2-8, 10-13, 16-22, and 38 for at least this reason.

Obviousness Rejections

Appellant again notes that the Examiner did not respond to the Appellant's repeated arguments that Carr is an improper reference under 35 U.S.C. § 103 for claims entitled to the priority date of provisional application 60/405791. As discussed above, Carr is not a proper reference under 35 U.S.C. § 103 to at least Claims 38, 2-8, 10-13, 16, and 27. Accordingly, Appellant submits that Claims 38, 2-8, 10-13, 16, and 27 are not made obvious by Carr

With what appears to be directed to Claims 33-37 and 39-45, the Examiner ***newly*** found that "The adjustment of fat content is well-within the skill of the art. If a low fat product is desired the fat content may be decreased and if the higher fat product is desired the fat content of the starting materials may be increased." Examiner's Response at page 7. Appellant disagrees with this new finding by the Examiner. Appellant submits that the Examiner has only provided a conclusory statement that is not sufficient under *KSR*. Appellant submits that the combination proposed by the Examiner is improper for at least this reason.

Appellant also submits that there is no reason to make higher fat products in view of Carr and Sadowsky. Example 9 of Carr discloses forming a milk solution containing 5.36% fat (Carr at page 12, line 18), which is not enough fat to qualify as cream under the FDA Standards of Identity. Sadowsky also fails to disclose a method for making ***cream***. Sadowsky discloses a method for incorporating concentrated milkfat into milk to form a slurry. Col. 5, ll. 30-50. Sadowsky discloses that "[g]enerally, the amount of concentrated milkfat added to the first portion of the reduced-fat raw milk is about 4 to about 10 percent." Col. 5, ll. 43-45. Example 1 of Sadowsky discloses forming a slurry with 8.4% fat. Example 2 of Sadowsky discloses forming a slurry with 3.9% fat. The slurries disclosed in Sadowsky are not cream because they do not have enough fat to qualify as cream under the FDA Standards of Identity. Carr and Sadowsky disclose making products with specific fat contents. There is no reason or benefit in Carr or Sadowsky to produce a higher fat product. The Examiner has also only provided a conclusory reason to increase the fat content. Appellant further submits that a person of skill in the art would appreciate that you cannot always decrease or increase the amount of fat in a particular product to any amount, as the fat content depends on the desired properties of the particular product. Thus, a person of skill in the art, especially without any reason or benefit to do so,

would not modify the process of Carr or Sadowsky as proposed by the Examiner to achieve a product with a higher fat level. Accordingly, the combinations proposed by the Examiner are improper.

Moreover, even if the combination of Carr and Sadowsky is proper, one skilled in the art would have no reasonable expectation of success. *Pharmastem Therapeutics v. Viacell, Inc.* 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007) (after *KSR*, Federal Circuit finds claims non-obvious for lack of indication of reasonable expectation of success for asserted combination). The modification proposed by the Examiner to increase the fat content also requires increasing the amount of fat in Carr or Sadowsky without any benefit, reason, or guidance of how to do so. Increasing the fat content, as suggested by the Examiner, would result in a different product with different processing concerns. Therefore, a person of skill in the art would have no reasonable expectation of success for making a product with higher fat content, as suggested by the Examiner.

For the above reasons, Appellant respectfully requests withdrawal of the rejections of Claim 33 and its dependents.

For similar reasons, the combination of Carr and Sadowsky is also improper with respect to Claims 39-45. Claims 39-42 recite, respectively, that "the first food product comprises high fat cream", "wherein the high fat cream comprises 70% fat or greater", and "wherein the first food product comprises plastic cream". Claims 43-45 recite, respectively, "wherein the cream comprises more than 36% fat", "wherein the cream comprises high fat cream", and "wherein the cream comprises plastic cream."

As discussed above, there is no reason to modify Carr or Sadowsky to produce a food product with the recited fat contents. A person of skill in the art would also have no reasonable expectation of success to modify Carr or Sadowsky to make products with the recited fat contents. Accordingly, Appellant respectfully submits that Claims 39-45 are not made obvious by Carr and Sadowsky for at least this reason.

Conclusion

In view of the foregoing arguments distinguishing Claims 2-8, 10-13, 16-22, 27, and 33-45 over the art of record, Appellants respectfully requests that the rejection of these claims be reversed.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 18, 2010

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CLAIMS APPENDIX

2. The method of Claim 38, further including adding an ingredient to the first food product in order to form a second food product.

3. The method of Claim 2, wherein the additional ingredient is milk.

4. The method of Claim 38, wherein the first food product is a dairy product.

5. The method of Claim 4, wherein the first food product is cream.

6. The method of Claim 5, wherein the cream is combined with milk to produce a second food product.

7. The method of Claim 6, wherein the second food product is used to make cheese.

8. The method of Claim 38, wherein the concentrated protein is a dehydrated protein.

10. The method of Claim 38, wherein the concentrated protein comprises casein.

11. The method of Claim 38, wherein the concentrated protein is nonfat dry milk.

12. The method of Claim 38, wherein the concentrated fat comprises milk fat.

13. The method of Claim 12, wherein the concentrated fat comprises about 95% milk fat.

16. The method of Claim 38, wherein the ionic composition of the hydrated protein solution is adjusted by changing the ionic composition of the hydration water prior to mixing with the protein.

17. The method of Claim 16, wherein the ionic composition of the water is adjusted by adding a monovalent salt to the water.

18. The method of Claim 17, wherein the monovalent salt is sodium chloride.

19. The method of Claim 17, wherein the monovalent salt is added to a concentration of about 0.25% to about 2.5%.

20. The method of Claim 38, wherein the ionic composition of the hydrated protein solution is adjusted by adding a monovalent salt to the solution after mixing with water.

21. The method of Claim 20, wherein the monovalent salt is sodium chloride.

22. The method of Claim 20, wherein the monovalent salt is added to a concentration of about 5 parts salt to about 15 parts salt per 100 parts protein.

27. The method of Claim 38, wherein the concentrated fat and hydrated protein are mixed in a high shear mixer or a high-pressure homogenizer.

33. A method of making cheese comprising:

mixing nonfat dry milk comprising milk proteins with water to form reconstituted skim milk, wherein the water comprises a monovalent salt prior to mixing;

combining the reconstituted skim milk with concentrated milk fat;

homogenizing the combined milk and fat to produce cream;

diluting the cream with milk to produce standardized milk; and

using the standardized milk to make cheese.

34. The method of Claim 33, wherein the water comprises from about 0.25 to about 2.5% of the monovalent salt.

35. The method of Claim 34, wherein the monovalent salt is sodium chloride.

36. The method of Claim 33, wherein the concentrated milk fat comprises about 95% anhydrous milk fat.

37. The method of Claim 36, wherein the concentrated milk fat comprises about 5% buttermilk powder.

38. A method of producing a food product from concentrated protein comprising:

mixing the concentrated protein with water to form a hydrated protein solution;

adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein, wherein the concentrated protein comprises concentrated milk protein; and

mixing the hydrated protein solution with a concentrated fat to form a first food product.

39. The method of Claim 38, wherein the first food product comprises high fat cream.

40. The method of Claim 39, wherein the high fat cream comprises 70% fat or greater.

41. The method of Claim 38, wherein the first food product comprises plastic cream.

42. The method of Claim 41, wherein the plastic cream comprises about 80% fat.

43. The method of Claim 33, wherein the cream comprises more than 36% fat.

44. The method of Claim 33, wherein the cream comprises high fat cream.

45. The method of Claim 33, wherein the cream comprises plastic cream.

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